

OPKO Health, Inc. (NASDAQ:OPK) 2020 Annual Meeting of Stockholders June 25, 2020 10:00 AM ET

Company Participants

Phillip Frost - Chairman and CEO
Dr. Jane Hsiao - Vice Chairman and CTO
Steve Rubin - Director & EVP
Adam Logal - SVP & CFO
Dr. Charles Bishop - CEO, Renal Division
Dr. Tony Cruz - CEO, Transition Therapeutic Subsidiary
Dr. Jon Cohen - Executive Chairman of BioReference Laboratories
Rulfo Hernandez - Inspector of Elections
Dr. Robert Fishel - Board Member
Dr. Richard Krasno - Board Member
Dr. Richard Lerner - Board Member
Mr. John Paganelli - Board Member
Mr. Richard Pfenniger - Board Member
Dr. Alice Yu - Board Member
Dr. Anthony Japour - Board Member

Phillip Frost

Good morning and welcome to the 2020 Annual Meeting of Stockholders of OPKO Health. I'm Phillip Frost, Chairman of the Board of Directors and CEO of the Company. I want to warmly welcome all of you virtually, express our appreciation for your support as we continue to build OPKO into leading pharmaceutical and diagnostics company.

I'm joined here by Dr. Jane Hsiao, who serves as Vice Chairman of the Board and Chief Technical Officer; Steve Rubin, who is a Director and Executive Vice President; Adam Logal, Senior Vice President and Chief Financial Officer; Dr. Charles Bishop, CEO of the Renal Division; and Dr. Tony Cruz, CEO of our Transition Therapeutic subsidiary. Dr. Jon Cohen Executive Chairman of BioReference Laboratories is joining us virtually. Steve Rubin will act as secretary for today's meeting, and Mr. Rulfo Hernandez has been appointed as the Inspector of Elections.

I would also like to acknowledge our Board members who are joining us virtually today. Dr. Robert Fishel; Dr. Richard Krasno; Dr. Richard Lerner; Mr. John Paganelli; Mr. Richard Pfenniger; Dr. Alice Yu; and Dr. Anthony Japour. All of these individuals have distinguished backgrounds in business and science and our company is fortunate to have the benefit of their experience. As is our custom, we will conduct a business portion of the meeting first and then there will be a designated question and comment period immediately following the formal portion of the meeting.

Stockholders, who have logged into the meeting using their 16 digit control number, may ask questions in the designated field on the web portal. Out of consideration for others, please limit yourself to one question. So, we may not be able to answer every question received, we will do

our best to provide a response to as many questions as pertain to business of the meeting as possible. Our executive officers and representatives from our registered public accounting firm, Ernst & Young are also attending today's meeting through the webcast. They'll be able to assist with questions during the Q&A portion of the meeting. This meeting is being recorded. However, no one attending via the webcast is permitted to use any audio recording device.

Before we start the formal part of today's virtual meeting, I'd like to say a few words about our company's performance over the past year. First, I'm proud of our accomplishments and advancing our business plan. Second, I'm particularly proud of how quickly and how well we responded to the challenges and opportunities presented by the COVID-19 pandemic. Among the accomplishments of the last 12-months, here are a few highlights.

Along with Pfizer, last October, we reported positive top line results from the global Phase 3 trial of our long-acting human growth hormone somatrogon in children with growth hormone deficiency. The trial achieved its goal to show that our once weekly product is safe and non-inferior to the once daily competitor. Earlier this month, the full data set from somatrogon global Phase 3 pediatric trial was presented by the trial's principal investigator, Dr. Cheri Deal at the ENDO 2020 virtual conference.

Two weeks ago, we announced favorable top line results from the Phase III trial in Japan of somatrogon in children with growth hormone deficiency. As for the 4K, our final Local Coverage Determination for Medicare patients became effective as of December 30, 2019, and payments resumed as of that day. Since RAYALDEE was launched in late 2016, we've seen steady growth in the number of prescribers, the number of prescriptions, and, most important, sales.

In March, we reported favorable interim results of two ongoing label expansion trials of RAYALDEE, one of a Phase IV study in patients with Stage 3 or 4 chronic kidney disease and one of the Phase 2 trials in patients with Stage 5 CKD on dialysis. And in the beginning of June, we received FDA authorization to pursue a Phase 2 clinical trial RAYALDEE in patients with mild to moderate COVID-19. If this works out well, it would be extremely interesting because there's a unique mechanism of action which gives the scientific basis for this trial.

Regarding by BioReference Laboratories, we have the makings of a turnaround story. Under Jon Cohen's leadership, BRL has been focusing on a number of strategic initiatives. In the months leading up to March 2020, BRL began to show a strong signs of regaining financial and operational stability. BRL management was effectively responding to the significant cuts in reimbursement and required increased patient contributions that went along with it that were impacting the entire industry.

Then everything changed when COVID-19 arrived. A sharp and rapid decline in patient visits to physician offices because of a drop in the number of samples and decreased the top line for the routine and genetic testing. Yet that decline was offset significantly in both volume and revenues by our COVID-19 testing activities. BRL quickly established itself as a leader in COVID-19 testing, even while operating at one of the nation's disease epicenters.

I'm proud of the work by Jon and the entire BRL team, as they were rapid with the response and smart in determining which test platform is to utilize, scaling up capacity in an uncertain and fast

changing environment. We could detail there are many actions taken by BRL, but I'll summarize it by saying the highly dedicated and trained BRL staff, along with proven processes and procedures served BRL and our country very well.

The BRLs rolling COVID-19 testing was also a catalyst to increase awareness of the BRL, which is well positioned to thrive in the current environment, one of which COVID-19 infections continue to persist while the country returns to what is being called the new normal. The near future of OPKO Health rests on the shoulders of somatogon, Rayaldee, 4Kscore and the work at BioReference Laboratories. Yet, we're also carefully advancing the pipeline of additional drug candidates, utilizing our proprietary technologies, typically targeting underserved and orphan indications. We have a great team and I'm honored to be speaking with you on their behalf.

Now, continuing with the business portion of the meeting, I will ask Mr. Rubin, Secretary for the meeting to report in the requirements for the meeting.

Steve Rubin

Thank you Dr. Frost, and good morning to our stockholders. There are three requirements for today's meeting, all of which have been met.

First, the Board of Directors has adopted resolutions authorizing this meeting to be held today and establishing April 27, 2020 as the record date for determining stockholders entitled to notice of, and to vote at this meeting.

Second, we have received the Mailing Agent Affidavit of Distribution certifying that notice of this meeting -- together with the Company's proxy statement, proxy card, and 2019 Annual Report -- were mailed, on or about April 29, 2020, to each stockholder of record on the record date.

And third, consistent with the Company's bylaws, no advance notice has been given to the Company regarding any other business to be conducted at this Annual Meeting.

We have available for inspection online a certified list showing the stockholders of the Company at the close of business on April 27, 2020, the record date. The stockholder list shows that there were a total of 669,828,524 shares of common stock outstanding and entitled to notice of, and to vote at, this meeting. This list has also been available at the offices of the Company for examination by stockholders for at least 10 days prior to this meeting.

We are informed by the inspector of election that a total of 544,797,223 shares of common stock are present in person or represented by proxy at this meeting. This represents approximately 81.33% of the outstanding shares of common stock as of the record date. Since this represents more than a majority of the voting power of all issued and outstanding stock entitled to vote on the record date, a quorum is present for purposes of transacting business.

There are three proposals to be acted on at this meeting. Proposal One is the election of the following individuals to serve as Directors of the Company for a term ending at the 2021 Annual Meeting of Stockholders or until such time as their respective successors are duly elected and

qualified: Dr. Phillip Frost, Dr. Jane Hsiao, Mr. Steven Rubin, Dr. Robert Fishel, Dr. Richard Krasno, Dr. Richard Lerner, Mr. John Paganelli, Mr. Richard Pfenniger, Jr., and Dr. Alice Yu.

Proposal Two is a non-binding advisory vote to approve the compensation paid to the Company's named executive officers as disclosed in our 2020 proxy statement, and

Proposal Three is the ratification of the appointment of Ernst & Young LLP as the Company's independent registered public accounting firm for the fiscal year ending December 31, 2020.

At this time, the polls are open and we will conduct voting on all matters to be presented. Each share of common stock is entitled to one vote. Any stockholder who is logged into the online virtual meeting who hasn't yet voted or wishes to change their vote, may do so now by clicking on the "Vote Here" button found on the web portal screen and following the instructions provided. Stockholders who have sent in proxies or voted via telephone or internet and who do not wish to change their vote, do not need to take any further action.

While we allow time for stockholders who have not already done so to complete their voting, I would like to remind you that some of the statements made at this meeting may be considered forward looking. The Company cautions investors that results of future operations may differ from those anticipated. We urge you to review the cautionary statements and other information contained in the Company's filings with the Securities and Exchange Commission, including our Annual Report on Form 10-K for fiscal year 2019 which identifies certain factors that could cause actual results to differ materially from those projected in any forward looking statements made during the meeting. Copies of the Annual Report on Form 10-K and other filings are available online through the Company's website or through the Securities and Exchange Commission.

Dr. Frost

Now that everyone has had an opportunity to vote, I declare that polls are now closed for voting. I will now ask that Mr. Rubin please share the preliminary voting results.

Steve Rubin

I am pleased to report that all three Proposals have been duly approved by the requisite vote of the Company's stockholders. Each of the Company's director nominees has been elected to serve as a director until the 2021 Annual Meeting of Stockholders or until such time as their respective successors are duly elected.

The non-binding advisory vote on the proposal to approve the compensation of the Company's named executive officers and the proposal to ratify the appointment of Ernst and Young, LLP as the Company's independent registered public accounting firm have also been approved. A full tally of the votes will be published in an appropriate filing with the Securities and Exchange Commission.

Phillip Frost

Thank you. There being no further business to come before the meeting, the 2020 Annual Meeting of Stockholders of OPKO Health is now adjourned.

I'll now open to meeting for stockholder questions and comments. If you have a question pertinent to the business of today's meeting, please submit your question via the web portal now. Please be reminded that we will attempt to answer questions as time allows, but only questions that are related to the business of the meeting. Please limit yourself to one question.

Question-and-Answer Session**Phillip Frost**

First question is. When will the Company be profitable? I'll ask Adam to answer that.

Adam Logal

Sure. Thanks, Phil. So, as we look at the way the BioReference business has responded to the COVID crisis and the volumes coming off of that business.. Clearly, there is an opportunity in the near-term to show significant growth at BioReference, and given the durability that COVID looks like there could be a significant long-term opportunity within that line of business, which should generate significant revenues and profits and cash flows coming out of that work.

However, given the uncertainty with the COVID testing, we don't know how durable it will be over the long-term. As we continue to progress our development programs with Pfizer, there are significant near-term milestones that we'll receive as well. So, it could be that as soon as immediately that we could be turned profitable on an opportunistic basis with COVID, and in the long-term with our relationship with Pfizer, the milestones and profit sharing coming off of that line of business, so in the near-term.

Phillip Frost

Thank you. Question two is. What is your approximate cost of setting up a drive-up station for testing COVID-19? Adam, again.

Adam Logal

Yes, sure. So, we actually don't incur the costs of setting up to drive through locations. Those are principally managed by the state and local governments or with some of our partnership relationships that we've entered into with some of the pharmacy retail chains. So, we don't get into the detail drive up location, testing logistics aspects, it is purely out we do the testing for those, those drive up settings.

Phillip Frost

Question three. Because of the COVID-19 viruses, the government allowing OPKO permission to move more quickly with improving the use of any of the potential treatments that are in the pipeline for OPKO?

With one exception, generally no, but the exception is the trial that I alluded to during my presentation earlier of RAYALDEE for treating patients who are infected. So far, we've got very rapid consideration of our submission of the protocol for the trial. And if that's an indicator of the responsiveness to government agencies to what we're doing, it may be that, that's one program that could be accelerated.

Next question. Is the Company currently trying to come up with a COVID-19 vaccine?

Short answer, No.

Question five. Could you please provide updates on the status of your Claros platform, SARM, oxyntomodulin, pruritus drug and inhaler?

For the Claros platform, as you know, we got FDA approval for the PSA and we're currently working on the manufacturing to figure out how we can make it more economical so that the commercial success will be assured. We also have a few steps to go through with regulatory way before we can market it. We're also at the same time developing several other tests that have big potential we believe.

As far as the SARM is concerned, there is no trial going on now, but the last trial that we did, gave us a lot of information about the utility or the potential utility of this SARM in treating patients who are debilitated and are weak and could benefit from increase in muscle mass. And there's a whole variety of situations in that category and we have been developing protocols to test the drug, test our drug for that indication.

Oxyntomodulin is an interesting product that we've always had big potential and we're currently having discussions with at least one party about a possible cooperation to develop the product.

The pruritus drug and inhalers are both on the back burner because of priorities being in other areas.

Next is: Could you please share your thoughts about the increasingly large short position in the stock of your company? Do you want to answer that, Adam?

Adam Logal

Sure, I'll try. So, obviously, the short interest remains pretty significant with it, as a percentage of our float as well as the trading activity. I think the latest report we saw was nearly 117 million shares are short of the Company. So those are obviously very significant positions that certain funds have placed on the Company. I think given the operating performance that we're expecting out of the business in the near term and frankly into the long-term, we hope to encourage those short sellers to turn around and become buyers.

Phillip Frost

Also some of the short position is related to the convertible offering that we did some time ago. And that's fairly routine that that brings in a lot of shorting as part of the strategy to buy convertibles.

Sure. So, the next is How many shares does OPKO own of Cocrystal Pharma? And how many shares of ChromaDex does OPKO own?

Adam Logal

So, OPKO discloses its ownership in its quarterly financial statements. As of March 31st, we owned a little over 5% of Cocrystal Pharma and a little bit less than 1/10th over percent of ChromaDex.

Phillip Frost

Thank you. How significant do you believe BioReference's revenue will be to OPKO overall growth revenue in the future? Will BRL's long-term growth come from organic growth or will you consider acquisitions?

I think that the contribution will be significant. And so far as the future is concerned, there is every reason to believe that the extra business that we never anticipated from the COVID-19 will lead to other new business and stimulate and enhance the organic growth. We're already seeing evidence of that and that's really important.

And let's see. So far as acquisitions are concerned, that's something that we always have in the back of head rolling. If a great opportunity comes up, to be honest, so far for in the recent past, we haven't had the wherewithal to make an acquisition on favorable terms because our share price was not where we thought it should be used for acquisitions and the cash situation was not strong enough. Going forward, that may change and we'll have more opportunities.

What are the key milestones, which entitled OPKO Health to royalties regarding its partnership with Pfizer? Do such royalties include both genotropin and somatrogen?

Adam Logal

So, the milestone payments we're entitled to are related to regulatory approvals in three major regions. The first region is the U.S. region, the second is the European region, and the third is the Japanese region. So, each one of the regulatory approvals for the three different indications in which we'll pursue results in a milestone payment, as it relates to the profit sharing arrangement, it does include both the long-acting form of growth hormone as well as Pfizer's genotropin.

Phillip Frost

Thank you. Okay.

Phillip Frost

That concludes our 2020 Annual Meeting of stockholders. I want to sincerely thank all of you for attending this year's meeting and for the interest and support you've shown in the affairs of OPKO Health.

Operator

This concludes your call. You may now disconnect.